ATRB's decision. If the contract term or ordering period has one year remaining, the operation of the contract award-term feature will cease and the contract term or ordering period will not extend beyond the maximum term stated in the contract.

(f) Award terms that have not begun may be cancelled (rather than terminated), should the need for the items or services no longer exists. No equitable adjustments to the contract price are applicable, as this is not the same procedure as a termination for convenience.

(g) The decisions made by the ATRB or Term Determining Official may be made unilaterally. Alternate Dispute Resolution procedures shall be utilized when appropriate.

(End of Clause)

3452.224–70 Release of information under the Freedom of Information Act.

As prescribed in 3424.203, insert the following clause in solicitations and contracts.

RELEASE OF INFORMATION UNDER THE FREEDOM OF INFORMATION ACT (MAR 2011)

By entering into a contract with the Department of Education, the contractor, without regard to proprietary markings, approves the release of the entire contract and all related modifications and task orders including, but not limited to:

(1) Unit prices, including labor rates;

(2) Statements of Work/Performance Work Statements generated by the contractor;

(3) Performance requirements, including incentives, performance standards, quality levels, and service level agreements;

(4) Reports, deliverables, and work products delivered in performance of the contract (including quality of service, performance against requirements/standards/service level agreements);

(5) Any and all information, data, software, and related documentation first provided under the contract;

(6) Proposals or portions of proposals incorporated by reference; and

(7) Other terms and conditions.

(End of Clause)

3452.224–71 Notice about research activities involving human subjects.

As prescribed in 3424.170, insert the following provision in any solicitation where a resultant contract will include, or is likely to include, research activities involving human subjects covered under 34 CFR part 97:

NOTICE ABOUT RESEARCH ACTIVITIES INVOLVING HUMAN SUBJECTS (MAR 2011)

(a) *Applicable Regulations.* In accordance with Department of Education regulations on the protection of human subjects, title 34, Code of Federal Regulations, part 97 (''the regulations''), the contractor, any subcontractors, and any other entities engaged in covered (nonexempt) research activities are required to establish and maintain procedures for the protection of human subjects.

(b) *Definitions.* (1) The regulations define *research* as ''a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.'' (34 CFR 97.102(d)). If an activity follows a deliberate plan designed to develop or contribute to generalizable knowledge, it is research. Research includes activities that meet this definition, whether or not they are conducted under a program considered research for other purposes. For example, some demonstration and service programs may include research activities.

(2) The regulations define a *human subject* as a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or obtains identifiable private information. (34 CFR 97.102(f)). The definition of a human subject is met if an activity involves obtaining—

(i) Information about a living person by—

(A) Manipulating that person's environment, as might occur when a new instructional technique is tested; or

(B) Communicating or interacting with the individual, as occurs with surveys and interviews; or

(ii) Private information about a living person in such a way that the information can be linked to that individual (the identity of the subject is or may be readily determined by the investigator or associated with the information). Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that an individual can reasonably expect will not be made public (for example, a school health record).

(c) *Exemptions.* The regulations provide exemptions from coverage for activities in which the only involvement of human subjects will be in one or more of the categories set forth in 34 CFR 97.101(b)(1)–(6). However, if the research subjects are children, the exemption at 34 CFR 97.101(b)(2) (*i.e.*, research involving the use of educational tests, survey procedures, interview procedures or observation of public behavior) is modified by 34 CFR 97.401(b), as explained in paragraph

(d) of this provision. Research studies that are conducted under a Federal statute that requires without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter, *e.g.*, the Institute of Education Sciences confidentiality statute, 20 U.S.C. 9573, are exempt under 34 CFR 97.101(b)(3)(ii).

(d) *Children as research subjects*. Paragraph (a) of 34 CFR 97.402 of the regulations defines *children* as ''persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.'' Paragraph (b) of 34 CFR 97.401 of the regulations provides that, if the research involves children as subjects—

(1) The exemption in 34 CFR 97.101(b)(2) does not apply to activities involving—

(i) Survey or interview procedures involving children as subjects; or

(ii) Observations of public behavior of children in which the investigator or investigators will participate in the activities being observed.

(2) The exemption in 34 CFR 97.101(b)(2) continues to apply, unmodified by 34 CFR 97.401(b), to—

(i) Educational tests; and

(ii) Observations of public behavior in which the investigator or investigators will not participate in the activities being observed.

(e) *Proposal Instructions*. An offeror proposing to do research that involves human subjects must provide information to the Department on the proposed exempt and nonexempt research activities. The offeror should submit this information as an attachment to its technical proposal. No specific page limitation applies to this requirement, but the offeror should be brief and to the point.

(1) For exempt research activities involving human subjects, the offeror should identify the exemption(s) that applies and provide sufficient information to allow the Department to determine that the designated exemption(s) is appropriate. Normally, the narrative on the exemption(s) can be provided in one paragraph.

(2) For nonexempt research activities involving human subjects, the offeror must cover the following seven points in the information it provides to the Department:

(i) *Human subjects' involvement and characteristics:* Describe the characteristics of the subject population, including their anticipated number, age range, and health status. Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as children, children with disabilities, adults with disabilities, persons with mental disabilities, pregnant women, institutionalized individuals, or others who are likely to be vulnerable.

(ii) *Sources of materials:* Identify the sources of research material obtained from or about individually identifiable living human subjects in the form of specimens, records, or data.

(iii) *Recruitment and informed consent:* Describe plans for the recruitment of subjects and the consent procedures to be followed.

(iv) *Potential risks:* Describe potential risks (physical, psychological, social, financial, legal, or other) and assess their likelihood and seriousness. Where appropriate, discuss alternative treatments and procedures that might be advantageous to the subjects.

(v) *Protection against risk:* Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety of the subjects.

(vi) *Importance of knowledge to be gained:* Discuss why the risks to the subjects are reasonable in relation to the importance of the knowledge that may reasonably be expected to result.

(vii) *Collaborating sites:* If research involving human subjects will take place at collaborating site(s), name the sites and briefly describe their involvement or role in the research. Normally, the seven-point narrative can be provided in two pages or less.

(3) If a reasonable potential exists that a need to conduct research involving human subjects may be identified after award of the contract and the offeror's proposal contains no definite plans for such research, the offeror should briefly describe the circumstances and nature of the potential research involving human subjects.

(f) *Assurances and Certifications*. (1) In accordance with the regulations and the terms of this provision, all contractors and subcontractors that will be engaged in covered human subjects research activities shall be required to comply with the requirements for Assurances and Institutional Review Board approvals, as set forth in the contract clause 3452.224–72 (Research activities involving human subjects).

(2) The contracting officer reserves the right to require that the offeror have or apply for the assurance and provide documentation of Institutional Review Board (IRB) approval of the research prior to award.

(g)(1) The regulations, and related information on the protection of human research subjects, can be found on the Department's protection of human subjects in research Web site: *http://ed.gov/about/offices/list/ocfo/humansub.html*.

(2) Offerors may also contact the following office to obtain information about the regulations for the protection of human subjects and related policies and guidelines: Protection of Human Subjects Coordinator, U.S. Department of Education, Office of the Chief Financial Officer, Financial Management Operations, 400 Maryland Avenue, SW., Washington, DC 20202–4331, Telephone: (202) 245 8090.

(End of Provision)

3452.224–72 Research activities involving human subjects.

As prescribed in 3424.170, insert the following clause in any contract that includes research activities involving human subjects covered under 34 CFR part 97:

RESEARCH ACTIVITIES INVOLVING HUMAN SUBJECTS (MAR 2011)

(a) In accordance with Department of Education regulations on the protection of human subjects in research, title 34, Code of Federal Regulations, part 97 (''the regulations''), the contractor, any subcontractors, and any other entities engaged in covered (nonexempt) research activities are required to establish and maintain procedures for the protection of human subjects. The definitions in 34 CFR 97.102 apply to this clause. As used in this clause, *covered research* means research involving human subjects that is not exempt under 34 CFR 97.101(b) and 97.401(b).

(b) If ED determines that proposed research activities involving human subjects are covered (*i.e.,* not exempt under the regulations), the contracting officer or contacting officer's designee will require the contractor to apply for the Federal Wide Assurance from the Office for Human Research Protections, U.S. Department of Health and Human Services, if the contractor does not already have one on file. The contracting officer will also require that the contractor obtain and send to the Department documentation of Institutional Review Board (IRB) review and approval of the research.

(c) In accordance with 34 CFR part 97, all subcontractors and any legally separate entity (neither owned nor operated by the contractor) that will be engaged in covered research activities under or related to this contract shall be required to comply with the requirements for assurances and IRB approvals. The contractor must include the substance of this clause, including paragraph (c) of this clause, in all subcontracts, and must notify any other entities engaged in the covered research activities of their responsibility to comply with the regulations.

(d) Under no condition shall the contractor conduct, or allow to be conducted, any covered research activity involving human subjects prior to the Department's receipt of the certification that the research has been reviewed and approved by the IRB. (34 CFR 97.103(f).) No covered research involving human subjects shall be initiated under this contract until the contractor has provided the contracting officer (or the contracting officer's designee) a properly completed certification form certifying IRB review and approval of the research activity, and the contracting officer or designee has received the certification. This restriction applies to the activities of each participating entity.

(e) In accordance with 34 CFR 97.109(e), an IRB must conduct continuing reviews of covered research activities at intervals appropriate to the degree of risk, but not less than once a year. Covered research activities that are expected to last one year or more are therefore subject to review by an IRB at least once a year.

(1) For each covered activity under this contract that requires continuing review, the contractor shall submit an annual written representation to the contracting officer (or the contracting officer's designee) stating whether covered research activities have been reviewed and approved by an IRB within the previous 12 months. The contractor may use the form titled ''Protection of Human Subjects: Assurance Identification/Certification/Declaration of Exemption'' for this representation. For multi-institutional projects, the contractor shall provide this information on its behalf and on behalf of any other entity engaged in covered research activities for which continuing IRB reviews are required.

(2) If the IRB disapproves, suspends, terminates, or requires modification of any covered research activities under this contract, the contractor shall immediately notify the contracting officer in writing of the IRB's action.

(f) The contractor shall bear full responsibility for performing as safely as is feasible all activities under this contract involving the use of human subjects and for complying with all applicable regulations and requirements concerning human subjects. No one (neither the contractor, nor any subcontractor, agent, or employee of the contractor, nor any other person or organization, institution, or group of any kind whatsoever) involved in the performance of such activities shall be deemed to constitute an agent or employee of the Department of Education or of the Federal government with respect to such activities. The contractor agrees to discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent contractor without imputing liability on the